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EXAMINER

SMITH, L

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ART UNIT PAPER NUMBER

1813

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DATE MAILED: 12/03/92

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice re Patent Drawing, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449. 1 page
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ \_\_\_\_\_

**Part II SUMMARY OF ACTION**

- ☒ Claims 1-19 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- ☐ Claims \_\_\_\_\_ have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 1-19 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
- ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

15. The disclosure is objected to because of the following informalities: page 4, line 15, "infections" should be "infectious". Appropriate correction is required.

The following is a quotation of the first paragraph of 35  
5 U.S.C. § 112:

10       The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. The specification is objected to under 35 U.S.C. § 112,  
15 first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. The claims are drawn to a method of immunizing a human by administering a DNA transcriptional unit. However, the specification provides no support for a method of immunizing  
20 humans. There is no evidence that the DNA transcriptional unit was ever given to humans and subsequently evaluated for the efficacy of the claimed method. There is no supportive evidence that humans were protected against any disease as would be suggested by a method of immunizing. Therefore, because of the  
25 lack of guidance provided by the specification, it would require undue experimentation of one of ordinary skill in the art to make and/or use the invention.

Claims 8 and 17 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the

specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

5       A person shall be entitled to a patent unless--

10       (b) the invention was patented or described in a printed publication in this country or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

15       A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20       Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

25       17. Claims 1,8,11 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 90/11092. WO 90/011092 describes a method of delivery a pharmaceutical or immunogenic polypeptide in vivo to a vertebrate by introducing DNA coding for an antigen into the vertebrate (page 6, 7, 35-39, 49). The

method is used for immunizing vertebrates against infectious pathogens including viral diseases as well as treating patients with muscular diseases and slow or latent viral infections (page 55-57, 75-79). This essentially describes the invention as  
5 claimed.

18. Claims 2-7, 9-16, 18 and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over Hunt et al, 1988, in view of WO 90/11092. Hunt et al describe the influenza viral hemagglutinin H7 and the results of immunization of chickens (abstract and  
10 table 2). The H7 viral hemagglutinin is known to generate immune responses (page 3014). Also describe are plasmids containing the DNA coding for the H7 hemagglutinin. Hunt et al do not describe a method of immunizing by introducing a DNA transcriptional unit in vivo. However, WO 90/11092 describes a method of introducing  
15 polynucleotide, coding for an infectious antigen, into a vertebrate host. WO 90/11092 also describes the advantages of such a method over present method of immunization. Among the advantages is listed the fact that the method would satisfy the need to associate antigens with the proper class I major  
20 histocompatibility molecules on cell surfaces to elicit cytotoxic as well as humoral responses (pages 3-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the plasmid encoding the H7 hemagglutinin molecule as disclosed by Hunt et al in the  
25 immunization method disclosed by WO 90/11092 to immunize chicken against lethal infection caused by the influenza virus. It would

Serial No. 07/855,562  
Art Unit 1813

have been further expected, barring evidence to the contrary, that the method would be effective in generating both cell mediated and humoral immune responses against influenza.

19. Papers related to this application may be submitted to  
5 Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO FAX Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 FAX Center number is (703) 308-4227. The hours of operation of  
10 the center are 8:45 am - 4:45 pm, Monday - Friday.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynette F. Smith whose telephone number is (703) 308-3909.

Any inquiry of a general nature or relating to the status of  
15 this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Smith/lfs *KJS*  
December 1, 1992

*CM*  
CHRISTINE M. NUCKER  
SUPERVISORY PATENT EXAMINER  
GROUP 180